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| 10/694,579 | 10/27/2003 | Jayesh Mehta | 01017/39555 | 3753 |

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MARSHALL, GERSTEIN & BORUN LLP
Lynn L. Janulis, Ph.D.
Sears Tower
233 South Wacker Drive, Suite 6300
Chicago, IL 60606-6357

EXAMINER

WOODWARD, CHERIE MICHELLE

| | |
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| ART UNIT | PAPER NUMBER |
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1647

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/694,579 | Applicant(s) MEHTA ET AL. | |
| | Examiner Cherie M. Woodward | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-12, 14, 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Formal Matters

1. Applicants' Amendments and Remarks, filed 14 February 2006, are acknowledged. Claims 1-12, 14, 17-19 are pending. Claims 13, 15, and 16 have been cancelled by Applicants. Claim 8 is withdrawn as being drawn to a non-elected invention. Claims 1-12, 14, and 17-19 are under examination. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections Withdrawn

2. The rejection of claims 1 and 5 under 35 U.S.C. 112, first paragraph, for scope of enablement, regarding the method of improving wall thickness following ischemia and reperfusion, is withdrawn. Applicants' arguments filed 14 February 2006 have been fully considered and they are persuasive. Applicants' Amendments of 20 May 2005 are acknowledged.

3. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, for scope of enablement, regarding the application of IL-8 to reduce myocardial infarct-related damage, is withdrawn. Applicants' arguments filed 14 February 2006 have been fully considered and they are persuasive.

4. The rejection of claim 2 under 35 USC 112, first paragraph, scope of enablement, is withdrawn. Applicants' arguments filed 14 February 2006 have been fully considered and they are persuasive. Applicants' argue that Example 1 provides guidance that supports the use of G-CSF for reducing wall thickness losses and that post-infarct hypertrophy of the cardiac myocytes is not applicable to the instant method. Applicants' arguments, filed 14 February 2006, have been fully considered and are persuasive.

5. The rejection of claim 10 under 35 USC 112, first paragraph, scope of enablement, regarding the reduction in tissue damage in the improvement to a method of bypass surgery, is withdrawn in light of Applicants' arguments. Applicants' arguments filed 14 February 2006 have been fully considered and they are persuasive.

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6. The rejection of claims 3, 4, 6, and 7 under 35 USC 112, first paragraph, scope of enablement, is withdrawn in light of Applicants' arguments. Applicants' arguments filed 14 February 2006 have been fully considered and they are persuasive.

7. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, for reciting a broad range or limitation together with a narrow range or limitation is withdrawn in light of Applicants' amendments. Applicants' arguments filed 14 February 2006 have been fully considered and they are persuasive.

8. The rejection of claims 13, 15-16 under 35 U.S.C. 112, first paragraph, written description, new matter, is withdrawn in light of Applicants' cancellation of the claims. Applicants' arguments filed 14 February 2006 have been fully considered and they are persuasive.

9. The rejection of claims 11, 12, and 14 under 35 U.S.C. 112, first paragraph, written description, regarding new matter, is withdrawn in light of Applicants' arguments and identification of sufficient support in the specification, as originally filed. Applicants' arguments filed 14 February 2006 have been fully considered and they are persuasive.

10. The rejection of claims 13, 15-16 under 35 U.S.C. 102(b) as being anticipated by Orlic *et al.*, as evidenced by Gottlieb *et al.*, is withdrawn in light of Applicants' cancellation of the claims.

11. The rejection of claims 13, 15-16 under 35 U.S.C. 102(b) as being anticipated by Anversa *et al.* is withdrawn in light of Applicants' cancellation of the claims

Claim Rejections Maintained

35 USC 112, First Paragraph, Scope of Enablement

12. The rejection of claim 5 under 35 USC 112, first paragraph, scope of enablement, regarding the administration of IL-8, is maintained for the reasons of record in the Office Actions 10/20/2004, 3/22/2005, and 11/14/2005. Applicants' arguments and amendments, filed 14 February 2006 have been fully considered, but they are not persuasive. Applicants have amended claim 5 to delete neurotrophic factor and individual species of interleukins, including IL-8. However, Applicants' have failed to

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overcome the rejection with regard to “interleukins” because IL-8 is a species of interleukin that is included in the genus of interleukins. Because the species is taught in the art, it anticipates the genus.

As stated in the Office Action of 14 November 2005, Gzrelak *et al.*, teach a rise in immature hematopoietic progenitors, primarily peripheral blood mononuclear cells (PBMCs), following surgical trauma. Gzrelak *et al.*, note that IL-8 induces progenitor cell mobilization properties, but do not elaborate on whether the IL-8 reduced inflammation following surgical trauma. Laterveer *et al.*, teach the induction of hematopoietic progenitor cells after injection of hematopoietic growth factors, including G-CSF, GM-CSF, and SCF, followed by IL-8. Laterveer *et al.*, also teach that IL-8 creates a 17-fold increase in the number of circulating progenitor cells following saline injection in controls 15 minutes after injection (p. 1389, column 1, second paragraph and Figure 2, p. 1391). IL-8 is best known in the art as being chemoattractive for neutrophils, recruiting these phagocytic polymorphonuclear cells to sites of injury or tissue damage. It is well known that IL-8 is involved in granulocyte mobilization. IL-8 is considered to be inherently proinflammatory specifically because it recruits neutrophils to the sites of injury or trauma. Neither Gzrelak *et al.*, nor Laterveer *et al.*, contradict this well known fact. The recruitment of neutrophils to the site of myocardial infarct-related damage is a proinflammatory response because once activated, neutrophils and macrophages must move through the tissues to the site of trauma or injury in order clean up necrotic and apoptotic debris (see i.e. Kukielka *et al.*, J Clin Invest. 1995 Jan 95:89-103). Kukielka *et al.*, support the hypothesis that IL-8 participates in neutrophil-mediated myocardial injury by demonstrating the proinflammatory effects of IL-8 in the myocardium after ischemia and reperfusion.

35 USC 112, Second Paragraph

13. The rejection of claims 1-7, 9, and 11-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained. Applicants' arguments filed 14 February 2006 have been fully considered, but they are not persuasive.

The claims are drawn to the improvement of a method of reperfusion therapy for treating acute myocardial infarction in a mammal to reduce infarct-related myocardial tissue damage, the improvement consisting of administering an effective amount of a composition comprising Granulocyte Colony Stimulating Factor (G-CSF) polypeptide after AMI, but before, concurrently with, and or after reperfusion therapy and an improvement in a method of reperfusion therapy for treating occlusion in an artery in a mammal to reduce tissue damage. The claims teach methods of improvement of reperfusion therapy. However, the instant claims are drawn to administration before, with, and/or after reperfusion therapy,

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which extends the method outside the reperfusion therapy. It is unclear from the language of the claims whether the applicant is claiming an improvement on a method of reperfusion therapy (thereby necessarily limiting the improvement to the metes and bounds of the reperfusion therapy) or whether the applicant is claiming a method of treatment before, during, and/or after reperfusion therapy.

Applicants' argue that the method is fully supported by the specification and that the specification explains that reperfusion therapy for the treatment of AMI consists of primary angioplasty and/or administration of a thrombolytic agent, which can be accomplished mechanically or medically.

Applicants' arguments have been fully considered, but are not persuasive.

Applicants' arguments interpret the claim language narrowly. Although the claims are read in light of the specification, as written, they read on administration of G-CSF at any time before, during, and/or after reperfusion therapy. There are no limits in the claims or the specification such that one would know how long before reperfusion therapy one should administer G-CSF. For example, the claims, as currently written, read on the administration of G-CSF at any time before or after reperfusion therapy. As such, treatment of a cancer patient with G-CSF, who subsequently suffers an infarct 24 hours prior to reperfusion therapy would fall within the claimed method. Likewise, a cancer patient who receives G-CSF treatment 48 hours after receiving reperfusion therapy would fall within the claimed method. If it is Applicants' intention to claim the administration of G-CSF during medical, mechanical, or surgical reperfusion, as argued, then the claims should be amended to reflect this intent. It is the lack of a defined time period for the administration of G-CSF that renders the claims indefinite.

14. The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained. Applicants' arguments filed 14 February 2006 have been fully considered, but they are not persuasive.

The claims are drawn to an improvement in a method of bypass surgery for treating occlusion in an artery in a mammal to reduce tissue damage, the improvement consisting of administering an effective amount of G-CSF. The claims are drawn to administration before, with, and/or after bypass surgery, which extends the method outside the bypass surgery. It is unclear from the language of the claims whether the applicant is claiming an improvement on a method of bypass surgery (thereby necessarily limiting the improvement to the metes and bounds of the bypass surgery) or whether the applicant is claiming a method of treatment before, during, and/or after bypass surgery. As indicated *supra*, the lack of a defined time period for the administration of the G-CSF renders the claims indefinite.

35 USC § 102(b)

15. The rejection of claims 1, 2, and 9 under 35 U.S.C. 102(b) as anticipated by Orlic *et al.* is maintained for reasons of record in the office actions of 10/20/2004, 03/22/2005, and 11/14/2005. Applicant's arguments filed 12 August 2005, have been fully considered, but they are not persuasive.

Applicants reiterate their position that both Orlic *et al.*, and Anversa *et al.*, did not teach the instant invention as claimed. Applicants argue that both Orlic *et al.*, and Anversa *et al.*, administered their compositions comprising G-CSF prophylactically, prior to the occurrence of a myocardial infarction, and then again after the occurrence of a myocardial infarction. Thus, Applicants argue, that Orlic *et al.*, and Anversa *et al.*, teach an additional step, which is not required in the instant method. Applicants also argue that they have distinguished the presently-claimed subject matter in the context of steps of treatment, through the use of the term "consisting of" and that no need exists to further limit the claimed subject matter to use of compositions having no other component than G-CSF.

The claims recite an improvement on a method to reduce infarct-related myocardial tissue damage. Applicants argue that Orlic *et al.* teach mobilization of bone marrow cells "prior to acute myocardial infarction (AMI)". Orlic *et al.* also teach the administration of a composition comprising G-CSF three days following coronary artery ligation, demonstrating that this composition was given following ischemia and not merely prophylactically (p. 10344:column 2:line 16 and p. 10349:column 2:lines 5-7).

The Orlic *et al.*, reference teaches administration of a composition comprising G-CSF before and after AMI. As explained at length in the prior office actions and during the telephonic interview of 21 February 2006, the scope of claim 1 brings the present invention within the scope of the prior art. As previously discussed, the scope of claim 1 could be narrowed as to only encompass administration after AMI by including a statement of limitation such as "but not before AMI" or "only after AMI".

16. The rejection of claims 1-7 and 9-10 under 35 U.S.C. 102(b) as anticipated by Anversa *et al.*, is maintained for the reasons of record in the office actions of 10/20/2004, 03/22/2005 and 11/14/2005. Applicant's arguments filed 12 August 2005, have been fully considered, but they are not persuasive.

Applicants reiterate their position that both Orlic *et al.*, and Anversa *et al.*, did not teach the instant invention as claimed. Applicants argue that both Orlic *et al.*, and Anversa *et al.*, administered their compositions comprising G-CSF prophylactically, prior to the occurrence of a myocardial infarction, and then again after the occurrence of a myocardial infarction. Thus, Applicants argue, that Orlic *et al.*,

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and Anversa *et al.*, teach an additional step, which is not required in the instant method. Applicants also argue that they have distinguished the presently-claimed subject matter in the context of steps of treatment, through the use of the term "consisting of" and that no need exists to further limit the claimed subject matter to use of compositions having no other component than G-CSF.

The claims recite an improvement on a method to reduce infarct-related myocardial tissue damage. Anversa *et al.*, teach the administration of cytokines, including G-CSF for the treatment or therapy of infarct-related myocardial tissue damage at p. 1 (0006). The methods disclosed by Anversa *et al.* are drawn to treating cardiovascular diseases, including ischemia (the most common cause of which is myocardial infarction), and taking advantage of the regenerative properties of stem cells and cytokines that can restore cardiac function (p. 1: paragraph (0003) and p. 2: paragraph (0022), respectively). The methods disclosed by Anversa *et al.*, are also drawn to treating cardiovascular diseases, including ischemia, and define ischemic events as encompassing clinical scenarios such as bypass surgery (p. 1: paragraph (0003) and p. 2: (0014), respectively). Further, Anversa *et al.*, state that the administration of cytokines, including G-CSF, following ischemia involves neoangiogenesis and restores "structural and functional integrity to the infarcted area" (p. 3: paragraph (0038), p. 4: paragraph (0044)).

The methods taught by Orlic *et al.*, and Anversa *et al.*, have the same steps and the same starting materials (administration of a composition comprising G-CSF in an effective amount in a mammal suffering from ischemic vascular diseases including ischemic cardiomyopathy or myocardial ischemia) as the presently claimed methods. Any additional steps taught by Orlic *et al.*, or Anversa *et al.*, are not limiting as applied to the instant claims. So long as Orlic *et al.*, and Anversa *et al.*, teach each of the steps of the instant claimed methods (which they do), their teachings fully encompass the claimed methods herein. As such, the presently claimed methods are not distinguishable from the methods taught by Orlic *et al.*, and Anversa *et al.*

The Anversa *et al.*, reference teaches administration of a composition comprising G-CSF before and after AMI. As explained at length in the prior office actions and during the telephonic interview of 21 February 2006, the scope of claim 1 brings the present invention within the scope of the prior art. As previously discussed, the scope of claim 1 could be narrowed as to only encompass administration after AMI by including a statement of limitation such as "but not before AMI" or "only after AMI".

17. The rejection of claims 11, 12, 14, and 16 under 35 U.S.C. 102(b) as being anticipated by Orlic *et al.* as evidenced by Gottlieb *et al.*, is maintained for the reasons of record in the Office Action of

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11/14/2005. Applicants failed to respond to the rejection of these claims as being anticipated by Orlic *et al.*, as evidenced by Gottlieb *et al.*

18. The rejection of claims 11, 12, 14, and 16 under 35 U.S.C. 102(b) as anticipated by Anversa *et al.*, is maintained for the reasons of record in the Office Action of 11/14/2005. Applicants' failed to respond to the rejection of these claims as being anticipated by Anversa *et al.*

New Claim Rejections – 35 USC § 102 - Necessitated by Amendment

19. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

20. Claims 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Orlic *et al.* (PNAS 2001, previously cited in Office Actions of 10/20/2004, 03/22/2005 and 11/14/2005), as evidenced by Gottlieb *et al.*, (previously cited in the Office Action of 11/14/2005). The claims recite improvements in a method of reperfusion therapy where the reduction in damage is characterized by decreased infarct-related myocardial thinning; wherein the reduction in damage results in improved patient outcome.

Orlic *et al.*, teach improvement in cardiac function of mice after infarct-related myocardial tissue damage and treatment with G-CSF (p. 10347:column 2:first full paragraph), myocardial regeneration after infarct-related myocardial tissue damage and treatment with G-CSF (p. 10345:column 2:first full paragraph; p. 10347:column 1:second paragraph; and Figure 2, p. 10346), reduced scarring (encompassing reduced necrosis and apoptosis) of the myocardium after infarct-related myocardial tissue damage and treatment with G-CSF (p. 10345:column 2:first full paragraph; p. 10348:column 1:first paragraph; and Figure 1C), neoangiogenesis in the infarcted zone after infarct-related myocardial tissue damage and treatment with G-CSF (p. 10346:column 2:first paragraph). The anatomical restoration was accompanied by a dramatic reduction in post-MI mortality and remarkable recovery in ventricular performance; thus demonstrating that the reduction in damage results in improved patient outcome (p. 10347, column 2, second full paragraph).

21. Claims 17-19 are rejected under 35 U.S.C. 102(b) as anticipated by Anversa *et al.* (US 2002/0061587 A1, published May 23, 2002), previously cited in the Office Actions of 10/20/2004, 03/22/2005 and 11/14/2005). The claims recite improvements in a method of reperfusion therapy where the reduction in damage is characterized by decreased infarct-related myocardial thinning; wherein the

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reduction in damage results in improved patient outcome; wherein the interleukin is selected from the recited group.

Anversa *et al.*, teach the administration of cytokines, including G-CSF for the treatment or therapy of infarct-related myocardial tissue damage in several species of mammals at p. 1: paragraph (0006). The methods disclosed by Anversa *et al.* are drawn to treating cardiovascular diseases, including ischemia (the most common cause of which is myocardial infarction), and taking advantage of the regenerative properties of stem cells and cytokines that may restore cardiac function (p. 1: paragraph (0003) and p. 2: paragraph (0022), respectively). Furthermore, Anversa *et al.*, state that the administration of cytokines, including G-CSF, following ischemia involves neoangiogenesis and restores "structural and functional integrity to the infarcted area" (p. 3: paragraph (0038)). Myocardial regeneration and reduced scar formation (encompassing reduced necrosis and apoptosis) in the cytokine-treated mice is discussed (p. 15: paragraph (0180)). A more favorable outcome is discussed at pp. 29-30, paragraph (0331). The use of IL-3 is taught at p. 1, paragraph (0005).

***New Claim Rejections - 35 USC § 112, First Paragraph - Necessitated by Amendment
Scope of Enablement***

22. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a bypass surgery method for treating occlusion in an artery in a mammal to reduce tissue damage, does not reasonably provide enablement for prevention of tissue damage. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claim recites a bypass surgery method for treating occlusion in an artery in a mammal to reduce and prevent tissue damage. The specification does not reasonably provide enablement for prophylaxis (prevention) of tissue damage. in any species by any means. The skilled artisan cannot envision the prevention of tissue damage. Prevention involves "attacking" the underlying cause of the tissue damage; i.e., disrupting the mechanisms which give rise to the tissue damage *a priori*. The skilled artisan is aware that the causes of tissue damage in occluded arteries are multifactorial. For purposes of enablement, the specification must provide reasonable detail in order for those skilled in the art to carry out the invention. In this case, the specification must disclose a means of preventing tissue damage, regardless of the underlying causes of the tissue damage. The teachings of the specification do not enabled a person of ordinary skill in the art to make and use the claimed method of prophylaxis. Moreover, "[p]atent protection is granted only in

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return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.” *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d at 1366, 42 USPQ2d at 1005 (Fed. Cir.), cert. denied, 118 S. Ct. 397 (1997), (“Tossing out the mere germ of an idea does not constitute an enabling disclosure”).

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent Application Publication US2005/0186182 A1 (priority to 10 November 2003).

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CMW


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600